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08/002590

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/083,590 06/25/93 ARTAVANIS-TSAKONAS

S 7326015

EXAMINER

SCHEINER, T

ART UNIT

PAPER NUMBER

18

18M2/1103

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NEW YORK, NY 10036-2711

1806

DATE MAILED:

11/03/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 6/9/95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 68-74 and 90-92 are pending in the application.
Of the above, claims 90 is are withdrawn from consideration.
2. ☒ Claims 1-67 and 75-89 have been cancelled.
3. ☐ Claims are allowed.
4. ☒ Claims 68-74 and 91-92 are rejected.
5. ☐ Claims are objected to.
6. ☐ Claims are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on . Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on , has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed , has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ; filed on .
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Claims 1-67 and 75-89 have been canceled and claims 90-92 added by amendment. Claims 68-74 and 90-92 are pending in the application.

Newly submitted claim 90 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Original and amended claims 68-74 and newly presented claims 91 and 92 are directed to detection of the levels of Notch proteins in patient samples (classified in Class 435, subclass 7.23). Newly presented claim 90 is directed to detection of Notch RNA by hybridization (classified in Class 435, subclass 6). Not only is Notch RNA detected by an entirely different method (hybridization) requiring different steps and reagents than measurement of protein, but an increase or decrease in protein expression is not necessarily consistent with an increase or decrease in RNA levels, so the correlation between RNA levels and malignancy, disease or disorder of the nervous system or benign disproliferative disorder may not be the same as that between protein levels and these disorders.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 90 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP §21.03.

Claims 68-74 and 90-92 are rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The specification defines the terms "Notch protein" and "Notch derivative" but the definitions are so broad that the terms actually encompass epidermal growth factor (cysteine-rich EGF repeats are

characteristic of both EGF and the various Notch homologs). The specification is not enabling for correlating the presence of a malignancy, disease or disorder of the nervous system or benign disproliferative disorder with the levels of "Notch proteins" or "Notch derivatives" as those terms are broadly defined. The term "Notch homolog" is more descriptive of the proteins actually associated with malignancy, disease or disorder of the nervous system or benign disproliferative disorder.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

Claims 68-74, 91 and 92 are rejected under 35 U.S.C. 103 as being unpatentable over Ellisen et al (Cell, Vol. 66, pp. 649-661, August 23, 1991).

Ellisen et al disclose the human Notch homolog TAN-1 and suggest that alterations in the structure and/or expression of TAN-1 contribute to transformation or progression in some T cell neoplasms, and is also involved in neural differentiation. It would have been obvious for one of ordinary skill in the art to have screened for malignancy, diseases or disorders of the nervous system or benign disproliferative disorders by detecting alterations in Notch protein expression because Ellisen et al suggest that there is a correlation between aberrant Notch expression and malignancy, and disorders of the nervous system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Toni R. Scheiner whose telephone number is (703) 308-3983. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

TRS
10/29/95

